REMARKS

Claims 1-55 and 57-75 have been canceled. Claim 56 remains in this application. Claims 76-187 have been added, and are pending. All of the pending claims are believed to be in condition for allowance.

With respect to claim 56, the Examiner indicated in the November 5, 2003 Office Action that claim 56 was allowed. The Applicants appreciate the indicated allowance of claim 56, and have presented new claim 187 for consideration, which the Applicants respectfully submit is allowable for the same reasons as set forth in the Examiner's Statement of Reasons for Allowance of claim 56.

Applicants have canceled all of the other claims previously pending in this application and have presented new claims 76-186 for consideration. These claims particularly point out new and unobvious features of the invention which are not suggested by any references, and which particularly are not suggested by the four references cited and applied by the Examiner in the Office Action, namely, Pelz, Tao, Hatschek and Seponnen. Hence, consideration and allowance of these claims are respectfully requested, for at least the reasons set forth below.

Claim 76 is directed to a method for passively monitoring the physiology of a patient in a vibration environment in which a sensor comprising a polarized polymer film with piezoelectric properties is coupled with the patient for sensing mechanical activity of the patient, including activity associated with the physiology of the patient and activity caused by the vibration environment. No reference teaches or suggests those features.

Specifically, Pelz does not teach the use of a sensor comprising a polarized polymer film with piezoelectric properties. Instead, Pelz discloses a two-component detector system, including a strip-like conductor of undefined construction for detecting mechanical vibrations upon which a separate sensing element, *e.g.*, crystals, is mounted.

(Col. 4, ll. 26-30.) There is no suggestion in Pelz that either the detector or the conductor is a polarized polymer film with piezoelectric properties.

Likewise, Tao does not teach the use of a sensor comprising a polarized polymer film with piezoelectric properties. Instead, Tao refers to a "film-like" material (Col. 9, ll. 62-63), whose actual construction is never described.

Hatschek discloses an optoelectronic transducer, such as a laser light emitting diode or a photo diode (Col. 10, ll. 10-11).

Seponnen discloses a layer of piezoelectric material, such as PVDF film, used as a support for recording movements which depend on variations in the weight of the person being examined, but he does not teach or suggest the use of such material to measure mechanical activity of a patient in a vibration environment.

Nor would it have been obvious in light of the references to use a sensor comprising a polarized polymer film with piezoelectric properties for sensing mechanical activity of a patient in a vibration environment. While Seponnen describes the use of a polarized polymer film for detecting weight variations of a standing person in a controlled, vibration-free environment, there is no suggestion of using it to sense mechanical activity, such as small pressure variations or body motions associated with cardiac or respiratory functions in a vibration environment, where movement or shaking transmitted to the patient's body from the environment could potentially distort or mask the signal of interest from the highly sensitive film. In this regard, vibration presents a more difficult problem from the one presented by acoustic sounds in the environment around the patient.

Claims 77-88 depend from claim 76 and distinguish the invention from the references in the same manner as claim 76, and additionally distinguish the invention from the references by other features recited in the dependent claims.

In particular, dependent claim 79 specifies that the vibration environment comprises a helicopter. The problem of monitoring the physiology of a patient in a helicopter is especially challenging because of the extremely high noise and vibration present, and because certain vital signs, such as heart rate and respiration rate, typically fall within the same range of frequencies as helicopter-generated vibration. None of the four references cited by the Examiner teaches or suggests a method for monitoring the physiology of a patient in a helicopter.

Moreover, because of the potential overlap in frequency between signals of interest and the environmental vibration, the problem of extracting the signal of interest from the sensed signal in a helicopter was particularly challenging, and it would not have been obvious to use a highly sensitive sensor such as a polarized polymer film with piezoelectric properties for sensing mechanical activity of the patient's body. The temperature sensitivity of the polarized polymer film is a further reason why it would not have been obvious to use such a film as a sensor in a helicopter environment. Air movement within the helicopter can tend to cause thermal fluctuations in the film which can affect reading accuracy.

Independent claim 184 and dependent claims 185-186 are also directed to a method for passively monitoring the physiology of a patient in a helicopter environment. These claims specifically recite the steps of coupling a motion sensor with the patient and sensing mechanical activity of the patient associated with the physiology of the patient and the helicopter environment, which also is not taught or suggested by any reference.

Independent claim 89 is directed to a method for passively monitoring the physiology of a patient in an environment, comprising coupling a first sensor with the patient, coupling a second sensor with the patient at a location remote from the first sensor, sensing physiological parameters of the patient and conditions of the environment around the patient with both the first and second sensors, converting the sensed physiological parameters and environmental conditions into signals, correlating the

signals from the first and second sensors, and using the correlation to extract signals associated with the physiology of the patient.

Independent claim 99 is directed to a method for providing a plurality of sensors disposed along a patient's supporting surface, each of said sensors being capable of passively sensing physiological parameters of the patient and conditions due to the environment around the patient, sensing with each of the sensors physiological parameters of the patient and environmental conditions and converting the sensed physiological parameters and environmental conditions into signals. Independent claim 103 is directed to a method for coupling a plurality of independent sensors with the patient at different locations on the patient's body, sensing mechanical activity of the patient's body due to physiology and to environmental vibration at each of said locations and converting the sensed mechanical activity into a plurality of signals. In both cases, the signals between the sensors are correlated and the correlation is used to extract signals associated with the physiology of the patient.

Independent claims 107, 122 and 127 are directed to monitoring apparatus that uses a plurality of sensors capable of sensing both patient conditions and environmental or ambient related conditions and correlates the signals between sensors to extract signals associated with patient conditions.

In this regard, the present invention uses an approach that is entirely different from the references cited by the Examiner. Both Pelz and Tao teach the use of at least two sensors, one of which is a dedicated background sensor isolated from the patient's body. In the case of Pelz, the dedicated sensor consists of a sensing means used to detect background vibrations that are present. The signals from this dedicated sensor are then subtracted from the main sensor which monitors the physiological conditions of the patient. (Col. 6, ll. 56-65.) In Tao, a second microphone is sealed so as to be able to respond only to noise and extraneous signals, with the difference between the signal from this microphone and the signal from the microphone monitoring patient conditions being

used to cancel the noise from the patient monitoring microphone signal. (Col. 3, l. 65 – col. 4, l. 8; col. 8, ll. 18-59.) Neither reference teaches or suggests the particular correlation approach described by the aforementioned claims of the present invention. Moreover, nothing in Hatschek or Sepponen even remotely teaches or suggests any kind of method or apparatus for extracting signals associated with the physiology of a patient from signals affected by environmental conditions.

Claims 90-98, 100-102, 104-106, 108-121, 123-126 and 128-134 are dependent claims which depend from claims 89, 99, 103, 107, 122 and 127, respectively, and distinguish the invention from the references in the same manner as the claim from which they depend, and additionally distinguish the invention from the references by other features recited in the dependent claims.

In this regard, particular attention is drawn to claims 97-98 and 118-119, which call for a combination of approaches including correlation for extracting signals associated with the physiology of the patient notwithstanding environmental conditions. No reference even remotely teaches or suggests such a combination of approaches.

Independent claim 135 is directed to an apparatus for passively monitoring the physiology of a patient, comprising a plurality of sensors for passively sensing mechanical activity at a plurality of different locations on the patient's body, including at least one sensor adapted to be disposed in the area of the patient's extremities, and a processor for extracting signals due to cardiac activity of the patient by selectively omitting signals from sensors remote from the patient's extremities. Independent method claim 143 is directed to a method for passively monitoring the physiology of a patient, which includes the step of extracting signals associated with the cardiac activity of the patient by selectively omitting signals from sensors remote from the patient's extremities. No reference even remotely teaches or suggests those features.

Claims 137-138 and 144 depend from claims 135 and 143, respectively, and distinguish the invention from the references in the same manner as the claim from which

they depend, and additionally distinguish the invention from the references by other features recited in the dependent claims. In this regard, particular attention is called to claims 136 and 144, which call for at least one sensor located or adapted to be disposed on the patient's foot.

Independent claim 139 is directed to apparatus for passively monitoring the physiology of a patient, comprising a plurality of sensors for sensing mechanical activity at a plurality of different locations on the patients body and a processor for extracting signals due to cardiac activity of the patient by selectively comparing signals from different locations on the patient's body. Independent method claim 145 is directed to a method for passively monitoring the physiology of a patient, which includes the step of extracting signals associated with cardiac activity of the patient by selectively comparing signals from different locations on the patient's body. No reference even remotely teaches or suggests those features.

Claims 140-142 and 146 depend from claims 139 and 145, respectively, and distinguish the invention from the references in the same manner as the claim from which they depend, and additionally distinguish the invention from the references by other features recited in the dependent claims. In this regard, particular attention is drawn to claims 142 and 146, which call for transforming the signals into frequency signals including respiration and heart rate harmonics and differentiating respiration and heart rate harmonics by selectively comparing signals from different locations on the patient's body. None of the references even remotely teaches or suggests such a feature.

Independent claims 147, 151, 159 and 162 are directed to various methods or apparatus for passively monitoring the physiology of the patient, comprising at least two sensors, each sensor comprising a polarized polymer film with piezoelectric properties for sensing physiological parameters of the patient at different parts of the patient's body, the time difference between corresponding signals from the sensors being used to

determine pulse wave velocity or pulse wave travel time, which is converted to blood pressure data. No reference teaches or suggests those features.

In contrast, Hatschek determines blood pressure from measurements taken at two measuring locations on the same part of the body, *e.g.*, along the same arterial flow path. By taking measurements at different parts of the patient's body, the present invention is able to obtain a blood pressure reading even if one vessel in the body is blocked.

Claims 148-150, 152-154, 160-161 and 163-164 are dependent claims which depend from claims 147, 151, 159 and 162, respectively, and distinguish the invention from the references in the same manner as the claim from which they depend, and additionally distinguish the invention from the references by other features recited in the dependent claims.

Independent claim 155 is directed to an apparatus for passively monitoring the physiology of the patient, comprising a plurality of sensors for sensing physiological parameters of the patient at at least three different locations on the patient's body, the temporal separation between corresponding heart rate signals at said different locations being used to calculate the rate of pulse wave propagation through the patient's body, which is converted into signals corresponding to blood pressure data.

Method claims 165 and 170 are directed to methods for passively monitoring the physiology of a patient comprising coupling at least three sensors with the patient at three different locations, measuring pulse wave travel time (claim 165) or pulse wave velocity (claim 170) with the sensors and converting the pulse wave travel time or pulse wave velocity into blood pressure data.

No reference even remotely teaches or suggests those features. Specifically, no reference teaches or suggests using at least three sensors to take measurements at at least three different locations on the patient's body for determining blood pressure data. Nothing like that is even remotely taught or suggested by Hatschek or Pelz.

Claims 156-158, 166-169, and 171-174 depend from claims 155, 165 and 170, respectively, and distinguish the invention from the references in the same manner as the claim from which they depend, and additionally distinguish the invention from the references by other features recited in the dependent claims.

Independent claim 175 is directed to a method for passively monitoring the physiology of a moving patient, comprising coupling a first sensor with the patient, coupling a second sensor with the patient at a location remote from the first sensor, sensing mechanical activity of the patient due to physiological parameters and to extraneous movement of the patient's body with both the first and second sensors, converting the sensed mechanical activity into signals, correlating the signals between the first and second sensors, and using the correlation to differentiate between signals due to physiological parameters and signals due to extraneous movement.

Independent claim 179 is an apparatus claim for passively monitoring the physiology of a moving patient, likewise comprising at least two sensors, each of said sensors being configured for sensing mechanical activity of a patient due to physiological parameters and to extraneous movement at a different location on the patient's body, and differentiating between signals due to physiological parameters and signals due to extraneous movement by correlating the signals between the sensors.

Those features are not taught or suggested by any references. Pelz uses a plurality of detectors to measure a patient's body movements, heart beats, respiratory movements, snoring and other mechanical movements and sounds, which are converted into electrical signals and processed to separate out signals which are associated with the patient's body movements by removing signals which are more than twice the average amplitude. There is no suggestion of correlating signals between sensors, as described in the referenced claims. (Col. 5, l. 66 – col. 6, l. 4.)

Tao describes a movement monitor which uses a pressure responsive transducer for detecting breathing movement. A low pass filter is used to differentiate between the

normal movement signals of interest, which will fall within a specified range of frequencies, and to exclude all other extraneous frequencies. (Col. 7, ll. 55-61.) Once again, there is no teaching or suggestion of correlating signals between sensors, as described in the referenced claims..

Seponnen is directed to a method and apparatus for measuring quantities relating to a person's cardiac activity, in which a person stands on a measuring support that records movements depending on the person's weight. A band pass filter is used to eliminate the frequencies which include disturbing signals produced by the swaying of a standing person. (Col. 4, ll. 43-47.) Once again, there is no teaching or suggestion of correlating signals between sensors as described in the referenced claims.

The remaining claims 176-178 and 180-183 are dependent claims which depend from claims 175 and 179, respectively, and thus distinguish the invention from the references in the same manner as the claims from which they depend, and additionally distinguish the invention from the references by other features recited in the dependent claims.

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Conclusion

From the foregoing, it is apparent that the claims of the present application define numerous features not present in any of the references cited by the Examiner and that the claims are clearly patentable. Hence, Applicants respectfully request that the application be reconsidered, that the claims be allowed, and that a timely notice of allowance be issued in this case.

Should the Examiner have any questions concerning the above amendments or arguments, or any suggestion for amending the claims to obtain allowance, Applicants request that the Examiner contact the Applicants' attorney, Craig Bailey, at 3108245555.

Respectfully submitted,

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